REMARKS

Claims 1-24 are pending in this application. Claims 12-24 have been withdrawn from consideration deemed non-elected subject matter. Claims 1-11 were rejected under 35 U.S.C. § 103(a). The specification was objected to because of informalities.

By this amendment, claims 1, 8 and 11 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification. Support for the amendment to claim 1 is found, *inter alia*, at page 12, lines 10-13, at page 27, lines 15-26, and at page 31, lines 14-20.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Specification Objections

The disclosure has been objected to because a sequence on page 19 lacks a sequence identifying number and because uncapitalized trademarks were used. Applicants have herewith submitted a Sequence Listing and amended the specification to include a sequence identifying number. The specification has also been amended to capitalize the trademarks and to include generic terminology. Applicants respectfully request withdrawal of the specification objections.

Rejections under 35 U.S.C. §103

Claims 1-11 were rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Morton *et al.* (WO 95/15338, 1995, "Morton") in view of The Interferon Beta Multiple Sclerosis Study Group, *Neurology*, 1993, vol. 43, pp. 655-661 ("The MS Study"). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The amended claims are directed to a method of treating multiple sclerosis (MS) comprising administering pharmaceutically-effective amounts of cpn10 and IFN-β to an individual. In the claimed method, the therapeutic effect of administering cpn10 and IFN-β is greater than that of administering an equivalent amount of cpn10 or IFN-β alone.

The Examiner states that Morton teaches the use of chaperonin 10 (cpn10) for the treatment and relapse prevention of MS and acknowledges that Morton "fails to teach the administration of interferon β." Office Action, page 4. The Examiner also states that The MS Study teaches use of interferon β (IFN-β) for the treatment of MS. The Examiner then asserts that it would be obvious to one of ordinary skill in the art to combine the teachings in Morton and The MS

Study to administer IFN-β and cpn10 to treat MS. Applicants respectfully disagree with this assertion.

As described throughout the specification, the present invention is based on the discovery that interferon β and chaperonin 10 act via different mechanisms to co-operatively reduce EAE symptoms and decrease EAE relapse frequency. See, for example, page 5, lines 28-31; page 12, lines 1-17; page 24 lines 15-29; page 31, lines 14-20; page 32 line 23 to page 33 line 2; and page 33, lines 12-21. At page 32, lines 7-9, for example, the specification describes that IFN-β and cpn10 use different suppressor-inducer pathways to downregulate lymphocyte activity. Applicants demonstrate and describe that administration of IFN-β and cpn10 in combination give a greater suppression of EAE than either substance administered alone and therefore act synergistically (for example, in Example 6, at page 31, lines 16-17, and at page 33, lines 14-15).

Therefore use of IFN-β and cpn10 as a combined therapeutic treatment of multiple sclerosis is a more efficacious method of managing the disease and prevents the need for IFN-β to be administered at doses which evoke side effects in patients.

Applicants respectfully submit that there is no suggestion or motivation in the references or in the art to modify Morton or The MS Study to arrive at the claimed invention, *i.e.*, the administration of the combination of cpn10 and IFN-β such that the therapeutic effect is greater than that of administering an equivalent amount of either cpn10 or IFN-β alone.

Applicants further submit that neither Morton nor The MS Study, either alone or combined, provide a reasonable expectation of success of the claimed invention. Since there is no teaching or suggestion in the cited references of the co-operative effect of administering the combination of cpn10 and IFN-β, the cited references provide no expectation of success for the claimed methods.

In addition, there is no teaching or suggestion of the claimed invention in either Morton or The MS Study, either alone or combined.

Applicants respectfully submit that a *prima facie* case of obvious has not been made.

Even if it was argued that a *prima facie* case is made (which it decidedly is not), Applicants respectfully point out that the claimed method results in an unexpected and very different response than any predicted response that would flow from the teachings of Morton and The MS Study. The unexpected response associated with the claimed invention also is of practical significance and benefit as discussed in the specification. Use of IFN-β and cpn10 as a combined therapeutic treatment of MS is a more efficacious method of managing the disease and prevents the need for IFN-β to be administered at doses which evoke side effects in patients.

Thus, Applicants respectfully submit that the claimed invention is not obvious in view of the cited references.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

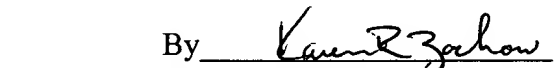
CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524372000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 5, 2003

Respectfully submitted,

By 

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